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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,919	03/08/2002	Kjell Olmarker	003300-914	1488

7590 10/16/2007
Benton S. Duffett, Jr.
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. Box 1404
Alexandria, VA 22313-1404

EXAMINER

MONDESI, ROBERT B

ART UNIT	PAPER NUMBER
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1652

MAIL DATE	DELIVERY MODE
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10/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/092,919	Applicant(s) OLMARKER, KJELL	
	Examiner Robert B. Mondesi	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-10 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-10 and 23-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10071009</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office action is in response to the amendment filed September 4, 2007.

Status of the Claims

Claims 1-3, 11-22 and 26-27 have been canceled. **Claims 4-10 and 23-25** are currently pending and under examination.

Information Disclosure Statement

The IDS filed October 9, 2007 has been received and is signed and considered, a copy of the PTO 1449 is attached to the following document.

Withdrawal of Objections and Rejections

The objections and rejections not explicitly restated below are withdrawn due to applicants' response in amendment filed September 4, 2007.

Maintenance of rejections

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4-10 and 23-25 remain rejected under 35 U.S.C. 102(e) as being anticipated by Reuben et al., United States Patent Application Publication US 2002/0072596.

The above rejection was explained in a previous Office action.

Response to applicants' arguments

In regards to the rejection of **claims 4-10 and 23-25** under 35 U.S.C. 102(e) as being anticipated by Reuben et al., applicants assert that **claim 23** has been amended to recite that the peptides derived from lactoferrin are those found at amino acid 12 to amino acid 40 of human lactoferrin and as previously noted, Ruben does not disclose peptides derived from amino acid 12 to amino acid 40 of human lactoferrin. Ruben further distinguishes between polypeptides and polypeptide fragments. Thus, Ruben does not disclose the peptide derivatives recited by the present claims.

Applicants' arguments have been considered but have not been found persuasive because the amendment to **claim 23** does not allow the examiner to comprehend which portion of the lactoferrin peptide the applicants are referring to. Furthermore "derived from" is not the same type of transitional phrase as "is", "set forth", "consists of" or even "comprises", see rejection of claims under 35 U.S.C. 112, second paragraph- below. The broadest reasonable interpretation of the claims allows for the citation of the above reference as prior art and as stated in the previous Office action, the applicants themselves have clearly stated on the record that Ruben discloses transferring sequences, two of which SEQ ID NO: 4 and SEQ ID No: 6 that can be derived from lactoferrin, see remarks page 1, paragraph 4, lines 1-2 in amendment filed March 26, 2007.

New Rejections and Objections

Specification

This application contains sequence disclosures at page 10, lines 11-12 that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in

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37 C.F.R. § 1.821(a)(1) and (a)(2). However, the fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below: Nucleic acid sequences of 10 or more nucleotides and amino acid sequences of 4 or more residues need to be designated with a sequence identifier. Wherein attention is directed to paragraph(s) §1.82 (c) and (e). Although an examination of this application on the merits can proceed without prior compliance, compliance with the Sequence Rules is required for the response to this Office action to be complete.

The amendment filed September 4, 2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicants have attempted to amend the specification in order to incorporate **essential material** that is disclosed in an International application (WO 00/01730). However it appears that applicants have misinterpreted examiners' citation of rule 1.57(f). Careful note must be made in reference to the distinction between **essential material** and **material**. Per rule 1.57(c): "Essential material" may be incorporated by reference, but **only by way of an incorporation by reference to a U.S. patent or U.S. patent application publication**, which patent or patent application publication does not itself incorporate such essential material by reference. "**Essential material**" is material that is necessary to: (1) Provide a written description of the claimed invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with

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which it is most nearly connected, to make and use the same, and set forth the best mode contemplated by the inventor of carrying out the invention as required by the first paragraph of 35 U.S.C. 112; (2) Describe the claimed invention in terms that particularly point out and distinctly claim the invention as required by the second paragraph of 35 U.S.C. 112; or (3) Describe the structure, material, or acts that correspond to a claimed means or step for performing a specified function as required by the sixth paragraph of 35 U.S.C. 112. Applicant is required to cancel the new matter in the reply to this Office Action.

As indicated by the previous citation of rule 1.57(f), applicants may incorporate **material** (non-essential) by way of amendment to the specification as long as a statement accompanies the amendment that the **material** is not new matter. Clearly, presently applicants have attempted to amend the specification in order to incorporate **essential material**, see amendment to **claim 23**; therefore this is not an accepted amendment to the specification because it has raised issues with regards to new matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-10 and 23-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is specifically a new matter rejection. Applicants' amendment to **claim 23** has introduced new matter to the claimed invention. As mentioned above the incorporation by reference to an international application is not the same as incorporation by reference to a US Patent or US Patent publication; therefore as a consequence applicants cannot introduce **essential material** that was previously disclosed in WO 00/01730 by way of reference. In this particular situation applicants have attempted to characterize the amino acid sequence of a peptide fragment derived from lactoferrin. Presently, the question is raised as to whether applicants' amendment to claim has raised new issues with regards to new matter. The failure to meet the written description requirement of 35 U.S.C. 112, first paragraph, commonly arises when the claims are changed after filing to either broaden or narrow the breadth of the claim limitations, or to alter a numerical range limitation or to use claim language which is not synonymous with the terminology used in the original disclosure. To comply with the written description requirement of 35 U.S.C. 112, para. 1, or to be entitled to an earlier priority date or filing date under 35 U.S.C. 119, 120, or 365(c), each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure

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Claims 4-10 and 24-24 are dependent claims that do not remedy the deficiencies of the independent claim that they are dependent from.

Claims 4-10 and 23-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants have amended **claim 23** in order to introduce the language a peptide derived from "amino acid 12 to amino acid 40 of human lactoferrin". Unfortunately there is no way the examiner can know what particular amino acid residues are being referred to here because there is no point of reference for any specific residue. Since there is no point of reference that the examiner can use, amino acids 12-40 can be any amino acids of lactoferrin as long as the mentioned peptide is 18 residues long. Furthermore, the claim states that the peptide is derived from and not "is", "set forth", "consists of" or even "comprises", the residues 12-40 of lactoferrin. A person of ordinary skill in the art would not be able to know what is being referred to as the amino acid sequence of the mentioned peptide. The examiner had previously suggested the submission of a SEQ ID NO: in order to overcome this particular rejection; however applicants have not decided to comply with the examiner's request.

Claims 4-10 and 24-24 are dependent claims that do not remedy the deficiencies of the independent claim that they are dependent from.

Conclusion

No claims are allowed

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert B Mondesi
Examiner
Art Unit 1652

Robert B. Mondesi
10-10-2007